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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,989	10/30/2001	Shunichi Shiozawa	2001-1298A	2860

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	10

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,989	Applicant(s) SHIOZAWA ET AL.	
	Examiner Carla J. Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4-8,10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election of Group I, claims 1-3 and 9 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The disclosure is objected to because of the following informalities:

The specification is objected to because it refers to a Figure 1 (see pages 4 and 13 of the specification). However, the present application does not contain a Figure 1.

3. Claims 1-3 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a disease gene for rheumatoid arthritis and a cDNA of said disease gene wherein the disease gene "encodes the cDNA of which the sequence from the 2679 to 2952nd bases is shown in SEQ ID NO: 1, which disease gene transcribes an mRNA encoding the cDNA of which the region from the 20th to 274th bases in SEQ ID NO: 1 is substituted with the sequence of SEQ ID NO: 2. The claims further include DNA fragments comprising SEQ ID NO: 3. The specification teaches cDNA differ from the wild-type Db1 cDNA (as defined by Ron et al. EMBO Journal. 1998. 7: 2465-2473) in that nucleotides 2698-2952 of the wild-type cDNA are deleted and nucleotides 1-61 of SEQ ID NO: 2 are substituted therefor. The claims as broadly written include nucleic acids in which sequences are present flanking the 10 mer of SEQ ID NO: 3. The claims also include "disease genes". Accordingly, the broadest reasonable

interpretation of the claims indicates that the claims are inclusive of genes and genomic sequences. However, the specification does not teach any full length genes or genomic sequences. In *The Regents of the Univerisity of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, the prior art teaches the wild-type Db1 cDNA and the specification teaches a single variant of this cDNA. The specification and prior art do not teach Db1 genomic sequences, such as intronic sequences or 3' or 5' untranslated sequences. In addition, the claims do not provide any meaninful limitations to define the structure or the function of the "cDNA of the disease gene". The claims include genomic and cDNAs comprising SEQ ID NO: 3 wherein the sequences flanking SEQ ID NO: 3 are not defined and the functional activity of the genomic and cDNA is not provided. However , the specification discloses only one Db1 variant

comprising SEQ ID NO: 3. The specification does not disclose any additional Db1 variants or other genes comprising SEQ ID NO: 3. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, chromosomal map position, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. While at the time of filing applicants were in possession of a cDNA that differs from the wild-type Db1 cDNA in that nucleotides 2698-2952 of the wild-type cDNA are deleted and nucleotides 1-61 of SEQ ID NO: 2 are substituted therefor, a representative number of species encompassed by the claimed genus of polynucleotides are not disclosed in the specification . The limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of full length Db1 disease genes, genomic Db1 nucleic acids, variants of a disease gene or cDNA defined only in terms of nucleotide positions 19/20-274 of SEQ ID NO: 1 or nucleotides 1-10 of SEQ ID NO: 3. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written.Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

4. Claims 1-3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and 9 are indefinite because it is unclear as to what is intended to be encompassed by the claimed disease gene. The claims define the disease gene in terms of nucleotides 2679-2952 as "shown in SEQ ID NO: 1". However, SEQ ID NO: 1 contains only 274 nucleotides. While the wild-type cDNA contains a fragment that includes nucleotide positions 2679-2952, it is confusing to claim the disease gene in terms of these positions with respect to SEQ ID NO: 1. Furthermore, the specification (page 4) indicates that it is nucleotide positions 19-274 of SEQ ID NO: 1 which are substituted with the sequences of SEQ ID NO: 2. Therefore, it is unclear as to whether the claims are intended to refer to nucleotides 19-274 or to nucleotides 20-274. It is also unclear as to what is intended to be meant by a mRNA encoding a cDNA and a disease gene which transcribes an mRNA.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gewirtz (U.S. Patent No. 5,612,212).

Gewirtz teaches a protooncogene which comprises the sequence of SEQ ID NO: 3. In particular, SEQ ID NO: 7 of Gewirtz contains nucleotides 5-14 which are identical to nucleotides

1-10 of instant SEQ ID NO: 3. It is noted that the recitation in the claims of a "disease gene of claim 1" and "a part of a cDNA of claim 2" does not further limit the structure or function of the claimed DNA fragments and the claimed DNA fragments are anticipated by the nucleic acids of Gewirtz which comprise SEQ ID NO: 3.

6. Claims 1-3 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kamai et al (Arthritis and Rheumatism (Sept 1999) 42(9 supplement) page S392; for meeting held Tuesday November 16, 1999).

It is noted that the authorship of the Kamai et al paper is distinct from the inventorship of the present application. Furthermore, Applicants are entitled to the priority date of only March 21, 2000 because a certified translation of foreign priority document JP 11116933 has not been provided.

Kamai et al disclose an isolated Db1 mutant nucleic acid, RA3, which differs from wild-type Db1 in that it contains a 223 bp deletion at the 3' end. The mutant Db1 nucleic disclosed by Kamai is considered to be identical to the presently claimed "disease gene for rheumatoid arthritis" and it is a characteristic of the the mutant Db1 nucleic acid of Kamai that it comprises present SEQ ID NO: 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703) 605-1237.

Carla Myers

April 22, 2002

CARLA J. MYERS
PRIMARY EXAMINER